CLAIMS

1. A composition for controlled delivery of at least one active substance into an aqueous medium by erosion at a preprogrammed rate of at least one surface of the composition, comprising

i) a matrix comprising the active substance, the matrix being erodible in the aqueous medium in which the composition is to be used, and

ii) a coating having at least one opening exposing at least one surface of said matrix, the coating comprising

a) a first cellulose derivative which has thermoplastic properties and which is substantially insoluble in the aqueous medium in which the composition is to be used,

and at least one of

b) a second cellulose derivative which is soluble or dispersible in water,

c) a plasticizer, and

d) a filler,

said coating being a coating which crumbles and/or erodes upon exposure to the aqueous medium, in particular a body fluid, at a rate which is equal to or slower than the rate at which the matrix erodes in the aqueous medium, allowing exposure of said surface of the matrix to the aqueous medium to be controlled.

2. A composition according to claim 1 wherein any exposed matrix surfaces erode at a substantially constant rate.

3. A composition according to claim 1 or 2 wherein, in the aqueous medium in which the composition is to be used, the coating does not completely crumble or erode before the matrix has completely eroded.

4. A composition according to claim 1 in which said first cellulose derivative is a cellulose ether which, when heated, is shapeable by molding or extrusion, including injection molding, blow molding and compression molding.

5. A composition according to claim 4 in which the cellulose ether comprises at least one ethylcellulose.

6. A composition according to claim 5 in which said ethylcellulose has an ethoxyl content in the range of 44.5-52.5%.

7. A composition according to claim 6 in which said ethylcellulose has an ethoxyl content in the range of 45.0-49.5%.

8. A composition according to claim 1 in which said first cellulose derivative is selected from the group consisting of cellulose acetate, cellulose propionate and cellulose nitrate.

9. A composition according to claim 1 in which said second cellulose derivative is selected from the group consisting of methylcellulose, carboxymethylcellulose and salts thereof, cellulose acetate phthalate, microcrystalline cellulose, ethylhydroxyethylcellulose, ethylmethylcellulose, hydroxyethylcellulose, hydroxyethylmethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxymethylcellulose and hydroxymethylpropylcellulose.

10. A composition according to claim 9 in which said salt of carboxymethylcellulose is selected from the group consisting of alkali metal and alkaline earth metal salts.

11. A composition according to claim 9 in which said second cellulose derivative is pharmaceutical quality hydroxypropylmethylcellulose.

12. A composition according to claim 1 in which said plasticizer is selected from the group consisting of phosphate esters; phthalate esters; amides; mineral oils; fatty acids and esters thereof with polyethylene glycol, glycerin or sugars; fatty alcohols and ethers thereof with polyethylene glycol, glycerin or sugars; and vegetable oils.

13. A composition according to claim 12 in which said fatty alcohol is selected from the group consisting of cetostearyl alcohol, cetyl alcohol, stearyl alcohol, oleyl alcohol and myristyl alcohol.

14. A composition according to claim 1 in which said plasticizer is a non-ionic surfactant.

15. A composition according to claim 1 in which said filler is selected from conventional tablet or capsule excipients.

16. A composition according to claim 15 in which the filler is a diluent, a binder, a lubricant or a disintegrant.

17. A composition according to claim 1 in which the matrix and/or the coating further comprises a water soluble antioxidant, a lipid soluble antioxidant and/or a preservative.

18. A composition according to claim 1 in which the matrix comprises a crystalline polyethylene glycol polymer and at least one non-ionic emulsifier dispersed in the polyethylene glycol matrix in an amount of 2-50% by weight of the crystalline polymer and the non-ionic emulsifier, the non-ionic emulsifier having at least one domain which is compatible with the polyethylene glycol polymer and being selected from fatty acid esters and fatty alcohol ethers, the active substance being substantially homogeneously dispersed in the polyethylene glycol matrix and/or located in geometrically well-defined zones within the matrix, the non-ionic emulsifier and/or the active substance reducing

the water affinity of domains between grains and in cracks in the crystalline polymer matrix and in the crystalline polymer matrix itself, thereby substantially eliminating water diffusion in the interface between the polymer crystals, so that erosion of the matrix is predominantly effected by the dissolving action of the aqueous medium on any matrix surfaces exposed to the medium.

19. A composition according to claim 18 in which the polyethylene glycol polymer has a molecular weight of at least 20,000 daltons.

20. A composition according to claim 19 in which the polyethylene glycol polymer has a molecular weight in the range of 20,000-35,000 daltons.

21. A composition according to claim 18 in which the polyethylene glycol polymer has a molecular weight of less than 20,000 daltons.

22. A composition according to claim 18 wherein the non-ionic emulsifier is a polyethylene glycol stearate.

23. A composition according to claim 1 wherein the matrix comprising the active substance comprises

d) a third cellulose derivative which has thermoplastic properties and which is substantially insoluble in the aqueous medium in which the composition is to be used,

and at least one of

e) a fourth cellulose derivative which is soluble or dispersible in water,

f) a second plasticizer, and

g) a second filler,

24. A composition according to claim 23 wherein said third cellulose derivative is of a type as defined in any one of claims 4-8.

25. A composition according to claim 23 wherein said fourth cellulose derivative is of a type as defined in any one of claims 9-11.

26. A composition according to claim 23 wherein said second plasticizer is of a type as defined in any one of claims 12-14.

27. A composition according to claim 23 wherein said filler is of a type as defined in claim 15 or 16.